K123410

APR 5 2013

510(k) Summary

Date Prepared 2-Apr-13

Healthy Sleep Dental Laboratory, Inc.
1271 East Broad Street
Columbus, OH 43205

Tel – 614-252-4444
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Official Contact: Todd Bacome – Laboratory Manager

Proprietary or Trade Name: Healthy Sleep Appliance

Common/Usual Name: Anti-snoring Device

Classification Code/Name: LRK – intraoral devices for snoring and OSA
21 CFR 872.5570
Class 2

Predicate Devices: K083209 – Acrylic Herbst Splint Appliance

Device Description:
The Healthy Sleep Appliance is a mandibular repositioning oral appliance used to treat snoring and mild to moderate obstructive sleep apnea. It is composed of an upper and a lower tray made to fit the occlusal surface of the teeth. These full arch trays are connected to each other by stainless steel arms that are set to conform to the predetermined occlusal relationship of the upper and lower arches. These arms have an adjusted length that can be adjusted as needed to exert a forward force on the lower jaw and advance the mandible relative to the maxilla. The advancement of the lower jaw increases the patient's pharyngeal space which facilitates improved air exchange.

Indications for Use:
The Healthy Sleep Appliance is intended for use in patients 18 years of age or older for the reduction of snoring and mild to moderate obstructive sleep apnea.

Patient Population: 18 years or older (Adults)

Predicate Device Comparison:

The Healthy Sleep Appliance has been compared to the predicate and is viewed as substantially equivalent because:

Indications –

- The Healthy Sleep Appliance is intended for use in patients 18 years of age or older for the reduction of snoring and mild to moderate obstructive sleep apnea. The predicate Herbst Splint Appliance (K083209) has the identical indications for use.

Discussion – The indications for use are identical to the predicate.

Patient Population –

- The patient population for both the Healthy Sleep Appliance and the predicate Herbst Splint Appliance (K083209) is patients 18 years or older.

Discussion – The intended patient population is identical to the predicate.

Technology –

- Both devices utilize an upper and a lower tray which are connected by 2 rods which hold advance the lower jaw.
- The Healthy Sleep Appliance has arms which are adjustable whereas the Herbst Splint (K083209) are a fixed length.

Discussion – The technology of both the devices are very similar and the difference of an adjustable side arm and the use of elastic bands to hold the mouth closed do not present significant differences. These differences do not raise any new safety risks or concerns.

Materials –

- The materials are standard dental grade materials which have been used in other cleared oral appliance.

Discussion – The materials are identical to other cleared oral appliance and a Material certification has been provided.

Differences –

There are no differences between the predicate and the proposed device which would raise any new safety or risks and thus can be found to be substantially equivalent.

Attributes	Healthy Sleep Appliance	Predicate Herbst Split Appliance K083208
Indications for Use	The Healthy Sleep Appliance is intended for use in patients 18 years of age or older for the reduction of snoring and mild to moderate obstructive sleep apnea.	The Arcylic Splint Herbst Appliance is intended for use in patients 18 years of age or older for the reduction of snoring and mild to moderate obstructive sleep apnea. The Arcylic Splint Herbst Appliance is worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The appliance is removable by the patient.
Patient Population	18 years of age or older	18 years of age or older
Design	2 full arch trays (upper and lower) made to fit the occlusal surface of the teeth	2 full arch trays (upper and lower) made to fit the occlusal surface of the teeth
Principle of Operation	Mandibular repositioning with 2 full arch trays connected to each other by side arms to conform to a predetermined occlusal relationship of the upper and lower arches	Mandibular repositioning with 2 full arch trays connected to each other by rod and tube assembly to conform to a predetermined occlusal relationship of the upper and lower arches
Prescriptive	Yes	Yes
Removable by the patient	Yes	Yes
Mechanism of adjustment	Arms have adjustable length that repositions the lower jaw forward. Adjusted is by the dentist.	Rod and tube assembly has an adjustable length that repositions the lower jaw forward. Adjusted is by the dentist.
Maximum adjustment	7 mm	7 mm
Materials	ISO 10993	ISO 10993
Single patient, multi-use	Yes	Yes

Non-clinical Testing Summary -

Biocompatibility of Materials –
The materials are standard dental grade materials which have been tested per ISO 10993 and shown to be biocompatible.

Clinical Testing Summary -

There have been clinical studies performed with similar device design, device usage, materials of construction, and technological characteristics which support a determination of substantial equivalence.

The cited study Ferguson, et.al., Oral Appliances for Snoring and Obstructive Sleep Apnea: A Review, SLEEP, vol.29, No. 2, 2006:244-262.

In addition we performed a seven patient clinical study was conducted comparing the Healthy Sleep Appliance vs. the predicate Herbst Splint (K083209). The objective of the study was to determine the success rate of the patient treatment using oral appliance therapy. Patient's underwent polysomnongraphy with pre- and port- treatment endpoints evaluated.

Subjects – 4 – female – age 31 – 55, 3 –males – age 45 - 58

Summary of pre- and post OA treatment - AHI

Subject	Gender / Age	Pre AHI	Post AHI
One (1)	Female / 39	101.1	2.1
Two (2)	Male / 58	46.3	5.2
Three (3)	Female / 55	9.9	4.0
Four (4)	Male / 45	34	1.5
Five (5)	Female / 31	30.5	.5
Six (6)	Male / 54	9	1.8
Seven (7)	Female / 45	6.2	0

AHI – Apnea / hypopnea index

- Note Subjects # 1, 2, 4, and 5 were diagnosed with severe OSA and Oral Appliance therapy was not recommended for them

In summary, the Healthy Sleep Appliance was well tolerated and effective with individuals with mild to moderate OSA that had not tolerated CPAP.

Substantial Equivalence Conclusion -

The sponsor has demonstrated through performance testing, design and features, non-clinical, and clinical testing that the proposed device and predicate have been found to substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 5, 2013

Health Sleep Dental Laboratory, Incorporated
C/O Mr. Paul E. Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
BONITA SPRINGS FL 34134

Re: K123410
Trade/Device Name: Healthy Sleep Appliance
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: March 20, 2013
Received: March 21, 2013

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer
-S FDA for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123410

Device Name: HEALTHY SLEEP APPLIANCE

Indications for Use:

The Healthy Sleep Appliance is intended for use in patients 18 years of age or older for the reduction of snoring and mild to moderate obstructive sleep apnea.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
Susan Runner, DDS, MA 2013.04.03
10:59:15 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123410